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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/346,270 11/23/94 GOODCHILD

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EXAMINER  
CRANE, L

12M2/0416

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ART UNIT PAPER NUMBER

7

1211

DATE MAILED: 04/16/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12/26/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ----- days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 17-19, 21-25, 27, 44-46, 48-52, 54-56, 58, 61 & 64 are pending in the application.

Of the above, claims ----- are withdrawn from consideration.

2. ☒ Claims 1-16, 20, 26, 28-43, 47, 53, 57, 59-60, 62-63 & 65-70 have been cancelled.

3. ☐ Claims ----- are allowed.

4. ☒ Claims 17-19, 21-25, 27, 44-46, 48-52, 54-56, 58, 61 & 64 are rejected.

5. ☐ Claims ----- are objected to.

6. ☐ Claims ----- are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on -----. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on -----, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed -----, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. -----; filed on -----.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

SN 08/346,270

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

## Art Unit 1211

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1200, Art Unit 1211.

5        Claims **1-16, 20, 26, 28-43, 47, 53, 57, 59, 60, 62-63 and 65-70** have been canceled.

10        Claims **17-19, 21-25, 27, 44-46, 48-52, 54-56, 58, 61 and 64** remain in the instant case. (Applicant's amendment incorrectly states that claims *61-64* have been amended when in fact only claims *61 and 64* remain in the case.)

15        The non-statutory double patenting rejection, whether of the obvious-type or non-obvious type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thompson*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

20        A timely filed terminal disclaimer in compliance with 37 C.F.R. §§1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with the application. See 37 C.F.R. §1.78(d).

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Effective January 1, 1994, an registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

5        Claims **17-19, 21-25, 27, 44-46, 48-52, 54-56, 58, 61**  
and **64** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the prior invention as set forth in claims **1-7 and 11-12** of prior U.S. Patent No. **4,806,263**. Although the conflicting claims are not identical ("263 claims "therapeutic compositions" and "methods of  
10        treating HTLV-III" and herein are claimed "compounds", "pharmaceutical compositions" and "methods of treating HTLV-III"), they are not patentably distinct from each other because the instant claims are directed to a portion of the subject matter claimed in the noted patented claims. As to the portion of the subject matter not  
15        claimed in the prior patent, namely "compounds", applicant is referred to *Ex Parte Billman*, 71 USPQ 253 wherein it is stated that "[whether]...the effective ingredient ... is carried by a solvent or a diluent does not change the effective character of the compound." This view is further supported by the more recent decision in *In re*  
20        *Rosicky*, 125 USPQ 341 wherein it is stated that "A known compound in association with a carrier is not a patentable composition." Therefore, it is presumed that the inverse proposition is also valid and renders the instant "compound" claims obvious in view of the patented pharmaceutical composition claims.

25        Claims **17-19, 21-25, 27, 44-46, 48-52, 54-56, 58, 61**  
and **64** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims

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1-6 of allowed U.S. Application No. **07/882,073**. Although the conflicting claims are not identical, they are not patentably distinct from each other because allowed claims **1-6** are directed only to oligonucleotide analogues effective to inhibit replication or gene  
5 expression of HTLV-III, while claims **17-19, 21-25, 27, 44-46, 48-52, 54-56, 58, 61 and 64** are drafted to include oligonucleotide analogues capable of inhibiting of replication or gene expression of an "infectious agent", specifying that agent to be HTLV-III in some claims, and pharmaceutical compositions thereof.  
10 As to the portion of the subject matter not claimed in the prior patent, namely "pharmaceutical compositions", applicant is referred to *Ex Parte Billman*, 71 USPQ 253 wherein it is stated that "[whether]...the effective ingredient ... is carried by a solvent or a diluent does not change the effective character of the compound."  
15 This view is further supported by the more recent decision in *In re Rosicky*, 125 USPQ 341 wherein it is stated that "A known compound in association with a carrier is not a patentable composition."

20 Applicant's arguments filed December 26, 1995 have been fully considered but they are not deemed to be persuasive.

Applicant has not filed any terminal disclaimers in the instant case to date. Therefore, the instant rejections have been maintained.

25 Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. §120, §121 or §365(c), applicant, under 35 C.F.R. §1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 C.F.R. §1.17(r) are filed prior to the filing of an appeal brief under 37 C.F.R. §1.192. Upon the timely filing of a first submission and the appropriate fee of **\$365** for a **small** entity under 37 C.F.R. §1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. §132, no amendment considered as a result of payment of the fee set forth in 37 C.F.R. §1.17(r) may introduce new matter into the disclosure of the application.

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If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 C.F.R. §1.17(r).

5 Papers related to this application may be submitted to Group 1800 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number for the FAX machine operated by Group 1200 is **(703) 308-4556**.

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-**308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kight, can be reached at (703)-308-1235.

20 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1200 receptionist whose telephone number is 703-**308-1235**.

LECrane:lec  
4/14/96



JOHN KIGHT  
SUPERVISORY PATENT EXAMINER  
GROUP 1200